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♦Practice Limited to
Federal Agencies

March 31, 2005

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*Mail Stop Amendment
Art Unit 1653*

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Re: U.S. Utility Patent Application
Application No. 09/529,130; § 371 Date: June 22, 2000
For: **Conjugates of Galactose-Binding Lectins and Clostridial Neurotoxins as Analgesics**
Inventors: Duggan *et al.*
Our Ref: 1581.0580000/RWE/ALS

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Credit Card Payment Form PTO-2038;
2. Sixth Supplemental Information Disclosure Statement;
3. Four (4) pages of Form PTO-1449 citing sixteen (16) documents;
4. Copies of six (6) cited documents; and
5. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Aaron L. Schwartz
Attorney for Applicants
Registration No. 48,181

RWE/ALS/law
Enclosures
377134v1

Sterne, Kessler, Goldstein & Fox PLLC. : 1100 New York Avenue, NW : Washington, DC 20005 : 202.371.2600 f 202.371.2540 : www.skgf.com



THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Duggan *et al.*

Appl. No.: 09/529,130

§ 371 Date: June 22, 2000

For: **Conjugates of Galactose-Binding
Lectins and Clostridial
Neurotoxins as Analgesics**

Confirmation No.: 2901

Art Unit: 1653

Examiner: Kam, Chih Min

Atty. Docket: 1581.0580000/RWE/ALS

**Sixth Supplemental Information Disclosure Statement
Under 37 C.F.R. § 1.97(c)**

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

*Mail Stop: Amendment
Art Unit 1653*

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Sixth Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Fifth Supplemental Information Disclosure Statement filed on December 9, 2004 in connection with the above-captioned application.

Copies of documents AS17 to AR19 are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents and patent application publications, documents AE1 to AK1, cited on the attached Form PTO-1449 are not submitted. In addition, copies of documents AS19 to AR20 are not provided in accordance with the U.S. Patent and Trademark Office OG notice of October 19, 2004, which states: "the requirement in 37 C.F.R. § 1.98(a)(2)(iii) for a legible copy of the specification, including the claims, and drawings of each cited pending U.S. patent application (or

portion of the application which caused it to be listed) is *sua sponte* waived where the cited pending application is stored in the USPTO's IFW system."

The Examiner's attention is directed to documents AE1-AK1, which are directed to related technical subject matter. The Examiner's attention is also directed to documents AS17-AR20, which are applications or prosecution histories of previously filed or co-pending patent applications which are directed to related technical subject matter. The identification of these U.S. Patent Applications and their respective prosecution histories are not to be construed as a waiver of secrecy as to those applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent

application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application. Attached is our PTO-2038 Credit Card Payment Form in the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p).

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Aaron L. Schwartz
Attorney for Applicants
Registration No. 48,181

Date: March 31, 2005

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(202) 371-2600
376453_1.DOC



FORM PTO-1449

SIXTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1581.0580000/RWE/ALSAPPLICATION NO.
09/529,130FIRST NAMED INVENTOR
Michael John Duggan§ 371 DATE
June 22, 2000ART UNIT
1653

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE1	6,395,513 B1	05/28/2002	Foster et al.			
	AF1	6,461,617 B1	10/08/2002	Shone et al.			
	AG1	6,632,440 B1	10/14/2003	Quinn et al.			
	AH1	2003/0147895 A1	08/07/2003	Shone et al.			
	AI1	2003/0166238 A1	09/04/2003	Shone et al.			
	AJ1	2004/0071736 A1	04/15/2004	Quinn et al.			
	AK1	2003/0049264 A1	03/13/2003	Foster et al.			

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes
	AM						No
	AN						Yes
	AO						No
	AP						Yes
							No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR			
	AS	17		Copy of application and Prosecution History for "Recombinant Toxin Fragments," Shone et al., U.S. Application No. 09/255,829, filed February 23, 1999
	AT	17		Copy of Application and Prosecution History for "Methods and Compounds for the Treatment of Mucus Hypersecretion," Quinn et al., U.S. Application No. 09/763,669, with a §371 date May 29, 2001

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.	



FORM PTO-1449

SIXTH SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENTATTY. DOCKET NO.
1581.058000/RWE/ALSAPPLICATION NO.
09/529,130FIRST NAMED INVENTOR
Michael John Duggan§ 371 DATE
June 22, 2000ART UNIT
1653

Page 2 of 4

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
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FOREIGN PATENT DOCUMENTS

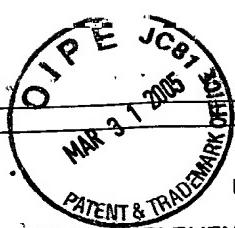
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>18</u>	Copy of Application and Prosecution History for "Delivery of Superoxide Dismutase to Neuronal Cells," Shone et al., U.S. Application No. 09/831,050, with a §371 date of August 20, 2001
	AS	<u>18</u>	Copy of Application and Prosecution History for "Constructs for Delivery of Therapeutics Agents to Neuronal Cells," Shone et al., U.S. Application No. 10/130,973, with a §371 date of June 25, 2002
	AT	<u>18</u>	Copy of Application and Prosecution History for "Recombinant Toxin Fragments," Shone et al., U.S. Application No. 10/241,596, filed September 12, 2002

EXAMINER _____ DATE CONSIDERED _____

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FORM PTO-1449

SIXTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1581.058000/RWE/ALSAPPLICATION NO.
09/529,130FIRST NAMED INVENTOR
Michael John DugganS 371 DATE
June 22, 2000ART UNIT
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	AL						Yes
	AM						No
	AN						Yes
	AO						No
	AP						Yes

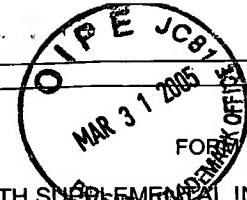
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>19</u>	Copy of Application and Prosecution History for "Methods and Compounds for the Treatment of Mucus Hypersecretion," Quinn et al., U.S. Application No. 10/633,698, filed August 5, 2003
	AS	<u>19</u>	Shone et al., "Delivery of Superoxide Dismutase to Neuronal Cells," U.S. Application No. 11/062,471, filed February 22, 2005
	AT	<u>19</u>	Shone et al., "Recombinant Toxin Fragments," U.S. Patent Application No. 11/077,550, filed March 11, 2005

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



	ATTY. DOCKET NO. 1581.058000/RWE/ALS	APPLICATION NO. 09/529,130
SIXTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	FIRST NAMED INVENTOR Michael John Duggan	
	§ 371 DATE June 22, 2000	ART UNIT 1653

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>20</u>	Shone et al., "Recombinant Toxin Fragments," U.S. Patent Application No. 10/527,411, filed March 11, 2005
	AS		
	AT		

EXAMINER	DATE CONSIDERED
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Quinn *et al.*

Appl. No. *To be assigned*

Filed: *Herewith*

For: **Methods and Compounds for the Treatment of Mucus Hypersecretion**

Art Unit: *To be assigned*

Examiner: *To be assigned*

Atty. Docket: 1581.0770001/RWE/BEC

Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of the documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/763,669, filed May 29, 2001, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not

be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Bruce E. Chalker

Bruce E. Chalker
Attorney for Applicants
Registration No. 47,480

Date: August 5, 2003

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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT		ATTY. DOCKET NO. 1581.0770001/RWE/BEC		APPLICATION NO. To be assigned	
		APPLICANT To be assigned			
		FILING DATE Herewith	GROUP To be assigned		

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AA1		4,873,346	10/10/1989	Anderson	548	157	09/20/1985
AB							
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
AL1		WO 95/17904	07/06/1995	WIPO			Yes No
AM1		EP 0 673 938 A2	09/27/1995	Europe			Yes No
AN1		WO 95/28171	10/26/1995	WIPO			Yes No
AO1		WO 95/33850	12/14/1995	WIPO			Yes No
AP1		WO 96/33273	10/24/1996	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	1	Fisher, C.E., et al., "Genetic construction and properties of a diphtheria toxin-related substance P fusion protein: In vitro destruction of cells bearing substance P receptors," Proc. Natl. Acad. Sci. USA 93:7341-7345, National Academy of Sciences USA (1996)
AS	1	Hambleton, P., "Clostridium botulinum toxins: a general review of involvement in disease, structure, mode of action and preparation for clinical use," J. Neurol. 239:16-20, Springer-Verlag (1992)
AT	1	Kurazono, H., et al., "Minimal Essential Domains Specifying Toxicity of the Light Chains of Tetanus Toxin and Botulinum Neurotoxin Type A," J. Biol. Chem. 267:14721-14729, American Society for Biochemistry and Molecular Biology, Inc. (1992)

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT		ATTY. DOCKET NO. 1581.0770001/RWE/BEC	APPLICATION NO. To be assigned
		APPLICANT To be assigned	
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U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	WO 97/13410	04/17/1997	WIPO			Yes No
	AM2	WO 98/07684	02/26/1998	WIPO			Yes No
	AN2	WO 98/07864	02/26/1998	WIPO			Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>2</u>	Nishiki, T., et al., "Identification of Protein Receptor for Clostridium botulinum Type B Neurotoxin in Rat Brain Synaptosomes," <i>J. Biol. Chem.</i> 269:10498-10503, American Society for Biochemistry and Molecular Biology, Inc. (1994)
	AS	<u>2</u>	Nishiki, T., et al., "The high-affinity binding of Clostridium botulinum type B neurotoxin to synaptotagmin II associated with gangliosides G ₁ b/G ₁ a," <i>FEBS Lett.</i> 378:253-257, Federation of European Biochemical Societies (1996)
	AT	<u>2</u>	Poulain, B., et al., "Inhibition of transmitter release by botulinum neurotoxin A. Contributions of various fragments to the intoxication process," <i>Eur. J. Biochem.</i> 185:197-203, Federation of European Biochemical Societies (1989)

EXAMINER	DATE CONSIDERED
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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT		ATTY. DOCKET NO. 1581.0770001/RWE/BEC	APPLICATION NO. To be assigned
		APPLICANT To be assigned	
		FILING DATE Herewith	GROUP To be assigned

U.S. PATENT DOCUMENTS

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	AA						
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FOREIGN PATENT DOCUMENTS

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	3	Zhou, L., et al., "Expression and purification of the Light Chain of Botulinum Neurotoxin A: A Single Mutation Abolishes Its Cleavage of SNAP-25 and Neurotoxicity after Reconstitution with the Heavy Chain," <i>Biochemistry</i> 34:15175-15181, American Chemical Society (1995)
	AS	3	International Search Report for PCT/GB99/02806, mailed March 16, 2000
	AT		

EXAMINER	DATE CONSIDERED
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Quinn *et al.*

Appl. No. *To be assigned*

Filed: *Herewith*

For: **Methods and Compounds for the Treatment of Mucus Hypersecretion**

Confirmation No.

Art Unit: *To be assigned*

Examiner: *To be assigned*

Atty. Docket: 1581.0770001/RWE/BEC

First Supplemental Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this First Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Information Disclosure Statement filed herewith in connection with the above-captioned application. Copies of the documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/763,669, filed May 29, 2001, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

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be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

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Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Bruce E. Chalker

Bruce E. Chalker
Attorney for Applicants
Registration No. 47,480

Date: August 5, 2003

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

FORM PTO-1449 <u>FIRST SUPPLEMENTAL</u> INFORMATION DISCLOSURE STATEMENT		ATTY. DOCKET NO. 1581.0770001/RWE/BEC	APPLICATION NO. To be assigned
		APPLICANT Quinn et al.	
		FILING DATE Herewith	GROUP To be assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB1	5,989,545	11/23/1999	Foster et al.	424	183.1	S 102(e) Date: 01/12/1998
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO2	WO 94/21300	09/29/1994	WIPO			Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR		
	AS		
	AT	3	Bizzini, B., "Investigation of the Mode of Action of Tetanus Toxin with the Aid of Hybrid Molecules Consisting in Part of Tetanus Toxin-Derived Fragments," <i>Bacterial Protein Toxins</i> , pp. 427-434, Academic Press London (1984).

EXAMINER	DATE CONSIDERED
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FORM PTO-1449 FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		ATTY. DOCKET NO. 1581.0770001/RWE/BEC		APPLICATION NO. To be assigned	
		APPLICANT Quinn et al.			
		FILING DATE Herewith		GROUP To be assigned	

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>4</u>	Blaustein, R.O. et al., "The N-terminal half of the heavy chain of botulinum type A neurotoxin forms channels in planar phospholipid bilayers," <i>FEBS Letters</i> 226:115-120, Elsevier Science Publishers B.V. (Biomedical Division) (December 1987).
AS	<u>4</u>	Hay, D.W.P., "Chronic obstructive pulmonary disease:emerging therapies," <i>Current Opinion in Chemical Biology</i> 4:412-419, Elsevier Science Ltd. (August 2000).
AT	<u>4</u>	Madison, J.M., and Irwin, R.S., "Chronic obstructive pulmonary disease," <i>The Lancet</i> 352:467-473, The Lancet Publishing Group (August 8, 1998).

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	5	Rogers, D.F., "Motor control of airway goblet cells and glands," <i>Respiration Physiology</i> 125:129-144, Elsevier Science B.V. (March 2001).
AS	5	Rogers, D.F., "Pharmacological regulation of the neuronal control of airway mucus secretion," <i>Current Opinion in Pharmacology</i> 2:249-255, Elsevier Science Ltd. (June 2002).
AT	5	Shone, C.C. et al., "A 50-kDa fragment from the NH ₂ -terminus of the heavy subunit of <i>Clostridium botulinum</i> type A neurotoxin forms channels in lipid vesicles," <i>Eur. J. Biochem.</i> 167:175-180, Springer International (August 17, 1987).

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Quinn *et al.*

Appl. No. *To be assigned*

Filed: *Herewith*

For: **Methods and Compounds for the Treatment of Mucus Hypersecretion**

Art Unit: *To be assigned*

Examiner: *To be assigned*

Atty. Docket: 1581.0770001/RWE/BEC

Second Supplemental Information Disclosure Statement

Commissioner for Patents
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Second Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' First Supplemental Information Disclosure Statement filed herewith, in connection with the above-captioned application. Copies of the documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/763,669, filed May 29, 2001, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

Document AP2, German Patent No. DE 197 35 105 A1, is in the German language. The relevance of Document AP2 can be ascertained by reference to Document AR6, which is an English-language abstract of this German patent.

Document AM4, WO 99/58571, is in the German language. The relevance of document AM4 can be ascertained by reference to Document AS6, which is an English-language abstract of this published international patent application.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on

information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

This Second Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Bruce E. Chalker

Bruce E. Chalker
Attorney for Applicants
Registration No. 47,480

Date: August 5, 2003

1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005-3934
(202) 371-2600

FORM PTO-1449 SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		ATTY. DOCKET NO. 1581.0770001/RWE/BEC	APPLICATION NO. <i>To be assigned</i>
		APPLICANT Quinn et al.	
		FILING DATE Herewith	GROUP <i>To be assigned</i>

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1						
	AB1						
	AC1	4,792,447	12/20/1988	Uhr et al.	424	85.91	05/27/1988
	AD1	5,668,255	09/16/1997	Murphy, J.R.	530	350	08/04/1993
	AE1						
	AF1						
	AG1						
	AH1						
	AI1						
	AJ1						
	AK1						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP2	DE 197 35 105 A1		Germany			Abstract/Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	6	Database - 12, English language abstract of DE 197 35 105 A1, at esp@cenet.				
AS	6	Dialog File 351, Accession No. 2000-072332, Derwent WPI English language abstract for WO 99/58571.				
AT						

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		ATTY. DOCKET NO. 1581.0770001/RWE/BEC	APPLICATION NO. <i>To be assigned</i>
		APPLICANT Quinn et al.	
		FILING DATE Herewith	GROUP <i>To be assigned</i>

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3	WO 91/09871	07/11/1991	WIPO			Yes No
	AM3	WO 92/15327	09/17/1992	WIPO			Yes No
	AN3	WO 93/04191	03/04/1993	WIPO			Yes No
	AO3	WO 93/15766	08/19/1993	WIPO			Yes No
	AP3	WO 96/12802	05/02/1996	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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	AS		
	AT		

EXAMINER

DATE CONSIDERED

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FORM PTO-1449 <u>SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</u>			ATTY. DOCKET NO. 1581.0770001/RWE/BEC		APPLICATION NO. <i>To be assigned</i>		
			APPLICANT Quinn et al.				
			FILING DATE Herewith		GROUP <i>To be assigned</i>		
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL4	WO 98/08540	03/05/1998	WIPO			Yes No
	AM4	WO 99/58571	11/18/1999	WIPO			Yes No
	AN4	WO 00/04926	02/03/2000	WIPO			Yes No
	AO4						Yes No
	AP4						Yes No
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
	AR						
	AS						
	AT						
EXAMINER					DATE CONSIDERED		
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.							

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Quinn *et al.*

Appl. No. *To be assigned*

Filed: *Herewith*

For: **Methods and Compounds for the Treatment of Mucus Hypersecretion**

Confirmation No.

Art Unit: *To be assigned*

Examiner: *To be assigned*

Atty. Docket: 1581.0770001/RWE/BEC

Third Supplemental Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Third Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Second Supplemental Information Disclosure Statement filed herewith in connection with the above-captioned application. A copy of each document is also provided.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

This Third Supplemental Information Disclosure Statement is being filed within three months of the filing date OR before the mailing date of a first Office Action on the merits. No statement or fee is required.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

B - E. Chalker

Bruce E. Chalker
Attorney for Applicants
Registration No. 47,480

Date: August 5, 2003

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Washington, D.C. 20005-3934
(202) 371-2600

FORM PTO-1449 THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		ATTY. DOCKET NO. 1581.0770001/RWE/BEC	APPLICATION NO. To be assigned
		APPLICANT Quinn et al.	
		FILING DATE Herewith	GROUP To be assigned

U. S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO4	WO 00/10598	03/02/2000	WIPO			Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR			
	AS			
	AT	6	Kielian, M., et al., Mechanisms of Mutations Inhibiting Fusion and Infection by Semliki Forest Virus," J. Cell Biol. 134:863-872, The Rockefeller University Press (1996)	

EXAMINER	DATE CONSIDERED
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FORM PTO-1449 <u>THIRD SUPPLEMENTAL</u> <u>INFORMATION DISCLOSURE STATEMENT</u>		ATTY. DOCKET NO. 1581.0770001/RWE/BEC		APPLICATION NO. To be assigned	
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U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
							Yes
							No
	AL						Yes
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	AM						Yes
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	AN						Yes
							No
	AO						Yes
							No
	AP						Yes

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	7	Kihara, A., and Pastan, I., "Analysis of Sequences Required for the Cytotoxic Action of a Chimeric Toxin Composed of <i>Pseudomonas</i> Exotoxin and Transforming Growth Factor α ," <i>Bioconjug. Chem.</i> 5:532-538, American Chemical Society (1994)
	AS	7	London, E., "Diphtheria toxin: membrane interaction and membrane translocation," <i>Biochim. Biophys. Acta</i> 1113:25-51, Elsevier Science Publishers B.V. (1992)
	AT	7	Murata, M., et al., "pH-Dependent Membrane Fusion and Vesiculation of Phospholipid Large Unilamellar Vesicles Induced by Amphiphilic Anionic and Cationic Peptides," <i>Biochemistry</i> 31:1986-1992, American Chemical Society (1992)

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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
	AR	8	Picard-Maureau, M., et al., "Foamy Virus Envelope Glycoprotein-Mediated Entry Involves a pH-Dependent Fusion Process," <i>J. Virol.</i> 77:4722-4730, American Society for Microbiology (April 2003)				
	AS	8	Plank, C., et al., "The Influence of Endosome-disruptive Peptides on Gene Transfer Using Synthetic Virus-like Gene Transfer Systems," <i>J. Biol. Chem.</i> 269:12918-12924, The American Society for Biochemistry and Molecular Biology, Inc. (1994)				
	AT	8	Prior, T.I., et al., "Translocation Mediated by Domain II of <i>Pseudomonas</i> Exotoxin A: Transport of Barnase into the Cytosol," <i>Biochemistry</i> 31:3555-3559, American Chemical Society (1992)				
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AL							Yes No
AM							Yes No
AN							Yes No
AO							Yes No
AP							Yes No
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
	AR	9	Seth, S., et al., "Activation of Fusion by the SER Virus F Protein: a Low-pH-Dependent Paramyxovirus Entry Process," J. Virol. 77:6520-6527, American Society for Microbiology (June 2003)				
	AS	2	Silverman, J.A., et al., "Mutational Analysis of the Helical Hairpin Region of Diphtheria Toxin Transmembrane Domain," J. Biol. Chem. 269:22524-22532, The American Society for Biochemistry and Molecular Biology, Inc. (1994)				
	AT	9	Wagner, E., et al., "Influenza virus hemagglutinin HA-2 N-terminal fusogenic peptides augment gene transfer by transferrin-polylysine-DNA complexes: Toward a synthetic virus-like gene-transfer vehicle," Proc. Natl. Acad. Sci. USA 89:7934-7938, National Academy Press (1992)				
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		APPLICANT Quinn et al.	
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U.S. PATENT DOCUMENTS

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>10</u>	Yao, Y., et al., "Membrane fusion activity of vesicular stomatitis virus glycoprotein G is induced by low pH but not by heat or denaturant," <i>Virology</i> 310:319-332, Academic Press (June 2003)
	AS		
	AT		

EXAMINER _____ DATE CONSIDERED _____

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